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STATE PASS TO DHHS/NIH/FIC FOR KEVIN BIALY

E.O. 12958: N/A  
TAGS: [TBIO](#) [KSCA](#) [OSCI](#) [BR](#)  
SUBJECT: APPROVAL OF NIH RESEARCH PROJECT TITLED "RETROVIRUS  
EPIDEMIOLOGY DONOR-STUDY II"

REFS: A) STATE 59955, B) BRASILIA 1081

1. On August 4, 2006, Embassy received from the Brazilian Ministry of Foreign Affairs, Division of Science and Technology, (DCTEC/MFA) an official notification (number 043, dated August 2, 2006) approving the research project proposal entitled "Retrovirus Epidemiology Donor-Study II", (number HB 047175). Informal translation of the approval notice follows:

Begin text:

"This is to inform that after consultation to the appropriate federal organs, the project titled "Retrovirus Epidemiology Donor-Study II", to be developed by Dr. Anna Barbara Carneiro-Proetti, from Fundacao Centro de Hematologia de Minas Gerais - HEMOMINAS; Dr. Thelma Therezinha Goncalvez, from Fundacao Pro-Sangue/Hemocentro de Sao Paulo; Dr. Divaldo de Almeida Sampaio, of Hospital das Clinicas da Universidade Federal de Pernambuco - HEMOPE and Dr. Ester Cerdeira Sabino, from Fundacao da Faculdade de Medicina de Sao Paulo, financially supported by the National Institutes of Health (NIH), was approved by the Brazilian Government. This research will not use human subjects in its first phase, and is therefore exempt from CEP - CONEP's evaluation.

Following the Ministry of Health's request, I am passing on such text with few remarks:

2)"According to the Ministry of Health's routine, copy of the protocol received was forwarded to the Brazilian researchers in order to have them attesting the accuracy of the document, in comparison to what should have been developed in the Brazilian territory. In response to that the researchers informed the following:

This is a preparatory phase, in which human subjects will not be involved. After the end of this phase (Phase 1), a new request will be sent to the Brazilian Government for approval of the second phase of the project (Phase 2).

At this moment the clinical protocols should be defined, and submitted to CONEP's approval. Phase-2 will only be initiated after total approval of the appropriate organs."

3)I emphasize that for the collection and transfer of data and/or biological material abroad, procedures should conform to current legislation.

Cordially,  
(signature)  
Everton Frask Lucero  
Head of the Division of Science and Technology"

End of text of translation.

2. The Embassy sees no adverse foreign policy implications with respect to this research project. We reiterate the importance of complying with Brazilian law on the export of data and biological

material and medical research involving human beings.

SOBEL